

## DEPARTMENT OF COMMERCE **Patent and Trademark Offic**

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| APPLICATION NO.                   | FILING DATE | FIRST NAMED INV           | ENTOR  | TA                    | TORNEY DOCKET NO. |  |
|-----------------------------------|-------------|---------------------------|--------|-----------------------|-------------------|--|
| 09/449,924                        | 12/02/99    | SAINT-LEGER               |        | Þ                     | 2365-12           |  |
|                                   |             | t shala on value or or or | $\neg$ | EXAMINER              |                   |  |
| HM12/1027<br>NIXON & VANDERHYE PC |             |                           |        | PULLIAM, A            |                   |  |
|                                   | GLEBE ROAD  |                           |        | ART UNIT PAPER NUMBER |                   |  |
| 8TH FLOOR<br>ARLINGTON            | VA 22201    | ·                         | •      | 1615                  | 1615 9            |  |
|                                   |             |                           |        | DATE MAILED:          |                   |  |
|                                   |             |                           |        |                       | 10/27/00          |  |

Please find below and/or attached an Office communication concerning this application or proceeding.

**Commissioner of Patents and Trademarks** 

|  | Application No.        | Applicant(s)                                 |       |  |  |  |  |  |
|--|------------------------|--|-------|--|--|--|--|--|
| Office Action Summary  | 09/449,924             | SAINT-LEGER, DIDIER                          |       |  |  |  |  |  |
| omee, was a canonia.   | Examiner               | Art Unit                                     |       |  |  |  |  |  |
|  | Amy E Pulliam          | 1615   |       |  |  |  |  |  |
| The MAILING DATE of this communication appears on the cover sheet with the correspondence address Period for Reply   |                        |  |       |  |  |  |  |  |
| A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.  |                        |  |       |  |  |  |  |  |
| <ul> <li>Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.</li> <li>If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.</li> <li>If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.</li> <li>Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).</li> <li>Status</li> </ul> |                        |  |       |  |  |  |  |  |
| 1)⊠ Responsive to communication(s) filed on <u>21 S</u>  | entember 2000          |  |       |  |  |  |  |  |
|  | s action is non-final. |  |       |  |  |  |  |  |
| 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under <i>Ex parte Quayle</i> , 1935 C.D. 11, 453 O.G. 213.   |                        |  |       |  |  |  |  |  |
| Disposition of Claims  |                        |  |       |  |  |  |  |  |
| 4) Claim(s) <u>1-13 and 18-22</u> is/are pending in the  | application.           |  |       |  |  |  |  |  |
| 4a) Of the above claim(s) is/are withdrawn from consideration.   |                        |  |       |  |  |  |  |  |
| 5) Claim(s) is/are allowed.  |                        |  |       |  |  |  |  |  |
| 6)⊠ Claim(s) <u>1-13, 18-22</u> is/are rejected.   |                        |  |       |  |  |  |  |  |
| 7) Claim(s) is/are objected to.  |                        |  |       |  |  |  |  |  |
| 8) Claims are subject to restriction and/or election requirement.  |                        |  |       |  |  |  |  |  |
| Application Papers   |                        |  |       |  |  |  |  |  |
| 9) The specification is objected to by the Examiner.   |                        |  |       |  |  |  |  |  |
| 10) The drawing(s) filed on is/are objected to by the Examiner.  |                        |  |       |  |  |  |  |  |
| 11) The proposed drawing correction filed on is: a) approved b) disapproved.   |                        |  |       |  |  |  |  |  |
| 12) The oath or declaration is objected to by the Examiner.  |                        |  |       |  |  |  |  |  |
| Priority under 35 U.S.C. § 119   |                        |  |       |  |  |  |  |  |
| 13)⊠ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).  |                        |  |       |  |  |  |  |  |
| a)⊠ All b)☐ Some * c)☐ None of the CERTIFIED copies of the priority documents have been:   |                        |  |       |  |  |  |  |  |
| 1.⊠ received.  | op. o p, acca          |  |       |  |  |  |  |  |
| 2. received in Application No. (Series Code / Serial Number)   |                        |  |       |  |  |  |  |  |
| 3. received in Application No. (Genes Gode / Genar Number)  3. received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).   |                        |  |       |  |  |  |  |  |
| * See the attached detailed Office action for a list of the certified copies not received.   |                        |  |       |  |  |  |  |  |
| 14) Acknowledgement is made of a claim for domestic priority under 35 U.S.C. & 119(e).   |                        |  |       |  |  |  |  |  |
| Attachmant(s)  |                        |  |       |  |  |  |  |  |
| Attachment(s)  | 40) 🗔 Internitorio     | (DTO 443) D= }                               | la(a) |  |  |  |  |  |
| <ul> <li>15) Notice of References Cited (PTO-892)</li> <li>16) Notice of Draftsperson's Patent Drawing Review (PTO-948)</li> <li>17) Information Disclosure Statement(s) (PTO-1449) Paper No(s)</li> </ul>   | 19) Notice of Informal | y (PTO-413) Paper N<br>Patent Application (F |       |  |  |  |  |  |

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## **DETAILED ACTION**

Receipt is acknowledged of the Request for Reconsideration, received September 21, 2000.

## Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless -

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-4, 6-12, and 22 are rejected under 35 U.S.C. 102(b) as being anticipated by WO 96/24329 to Blieszner *et al* (hereinafter WO '329). WO '329 discloses a personal care composition which includes water, dimethicone, a polymeric emulsifier, a water soluble polyol, a pH adjusting agent, an anti-microbial agent, and a chelating agent. WO '329 further discloses that the preferred antimicrobial agent includes 3-iodo-2-propynyl butyl carbamate (p 5, paragraph 2), and that the polyol may be chosen from a group including 1,2,4-butane triol, 1,2,6-hexane triol, and sorbitol (p 11, paragraph 4). Further, in the examples, WO '329 teaches that the polyol and the antimicrobial agent are present in amounts that fall within the range claimed by applicant. In addition, WO '439 teaches that additives, such as fragrances, skin smoothing aids, moisteners, humectants, emollients, powders (p 14, paragraph 2), silicone oils, and organic base pH adjusting agents can also be included (p 20, example

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a). Lastly, although the preferred embodiment of the composition disclosed by WO '329 is a wipe, they also teach that the composition may be administered through spraying, dripping, smoothing, massaging, or rubbing. It is the position of the examiner that this disclosure is broader than simply a wipe, and allows for other forms of application, and therefore it reads on the limitations of applicant's claim 12.

Applicant's arguments filed September 21, 2000 have been fully considered but are not found persuasive. Applicant argues that the cited document is teaching of a personal cleansing composition for protection against perineal dermititis, whereas applicant desires a composition for treating dandruff. However, the claims rejected above are composition claims referring to a cosmetic or dermatological composition, not method of treatment claims, and therefore this argument is spurious. Applicant further argues that page 5, paragraph 2 states that the preferred antimicrobial is a mixture. However, applicant uses comprising language in the claims, which allows for other components to be present in the composition. The expression "comprising permits the presence of other ingredients and does not preclude the presence of other ingredients, active or inactive even in major amounts . See Moleculon Research Corporation v CBS , Inc 229 USPQ 805; In re Baxter 210 USPQ 795, 803. Applicant further argues that WO '329 does not teach an alkanyl carbamate with a polyol in a ratio of 0.01 to 100. However, this is not true because as stated by applicant, the reference teaches 0.2% antimicrobial agent (which has the alkanyl carbamate claimed by applicant), and 1% polyol, and the ratio in this example is 0.2, which falls within applicant's claimed range. Therefore, this rejection is maintained.

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## Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claim 5 is rejected under 35 U.S.C. 103(a) as being unpatentable over WO '329 as applied to claims 1-4, 6-12 and 22 above. WO '329 does not teach the exact polyol claimed in claim 5. However, applicant teaches that many polyols can be used in the formulation and achieve the same effect. Further, WO' 329 does teach the inclusion of some of the polyols claimed by applicant in claim 4. Therefore, it is the position of the examiner that one of ordinary skill in the art would have been motivated to use any polyol in the formulation disclosed by WO '329, with the expected results being an equally successful antimicrobial composition. Therefore the invention as whole would have been *prima facie* obvious to one of ordinary skill in the art at the time the invention was made. The burden is shifted to applicant to disclose the criticality in the specific compound claimed in claim 5 of the instant application.

Applicant's arguments filed September 21, 2000 have been fully considered but are not found persuasive. Applicant again argues that the compositions are used for different purposes. This argument has been discussed above, and the rejection is maintained for the reasons stated above.

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Claims 1-13 and 18-22 are rejected under 35 U.S.C. 103(a) as being unpatentable over WO '329 as applied to claims 1-4, 6-12, and 22 above, and further in view of US Patent 5,552,425 to Merianos (hereinafter US '425). WO '329 teaches that the composition can be used to clean and disinfect the skin, but does not teach its use as a shampoo. US '425 discloses an antimicrobial composition which comprises 3iodo-2-propynyl butyl carbamate, as well as a glycol (abstract). US '425 further teaches that their composition can be used as a shampoo (c 36, claim 8). It is the position of the examiner that one of ordinary skill in the art would have been motivated to use the composition disclosed by WO '329 as a shampoo composition, in addition to a skin composition. The composition disclosed by WO '329 must be sensitive to the skin in order to be useful as a skin formulation, and therefore would not be harmful if applied to the scalp. Further, based on the disclosure of US '425, the active ingredient (IPBC) is acceptable is shampoo formulations. One of ordinary skill in the art would have expected a shampoo composition with the same antimicrobial properties achieved by the skin formulation. Therefore the invention as a whole would have been prima facie obvious to one of ordinary skill in the art at the time the invention was made.

Applicant's arguments filed September 21, 2000 have been fully considered but are not found persuasive. Applicant argues that the compositions are for different purposes. This is discussed by the examiner, but US '425 is relied upon to show that applicant's active ingredient is known in shampoo compositions and is known to have synergistic biocidal activity. The position of the examiner is that the disclosure of US

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'425 taken in light of WO '329 would motivate someone of ordinary skill in the art to use the composition of WO '329 as a shampoo, and to expect the same excellent antimicrobial properties. Therefore, this rejection is maintained.

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Amy E Pulliam whose telephone number is (703) 308-4710. The examiner can normally be reached on M-F 8:30-5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Thurman K Page can be reached on (703) 308-2927. The fax phone numbers for the organization where this application or proceeding is assigned are (703)

308-7922 for regular communications and (703) 308-7922 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-1234.

Amy E. Pulliam Patent Examiner Art Unit 1615 October 24, 2000

> THURMAN K PAGE SUPERVISORY PATEND EXAMINER TECHNOLOGY CENTER 1600